

EXHIBIT G

[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended September 30, 2021.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from _____ to _____.

Commission File Number 000-23357

INOTIV, INC.

(Exact name of the registrant as specified in its charter)

INDIANA	35-1345024
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2701 KENT AVENUE	47906
WEST LAFAYETTE, INDIANA	(Zip code)
(Address of principal executive offices)	
(765) 463-4527	
(Registrant's telephone number, including area code)	

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of exchange on which registered
Common Shares	NOTV	NASDAQ Capital Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by checkmark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. YES NO

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES NO

Based on the closing price on the NASDAQ Capital Market on March 31, 2021, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$172,225,000. As of December 1, 2021, 24,266,099 of registrant's common shares were outstanding.

[Table of Contents](#)**TABLE OF CONTENTS**

	<u>Page</u>
PART I	3
<u>Item 1. Business</u>	3
<u>Item 1A. Risk Factors</u>	29
<u>Item 1B. Unresolved Staff Comments</u>	43
<u>Item 2. Properties</u>	43
<u>Item 3. Legal Proceedings</u>	44
<u>Item 4. Mine Safety Disclosures</u>	44
PART II	44
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	44
<u>Item 6. Selected Financial Data</u>	45
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	45
<u>Item 7A. Quantitative and Qualitative Disclosures about Market Risk</u>	57
<u>Item 8. Financial Statements and Supplementary Data</u>	58
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	101
<u>Item 9A. Controls and Procedures</u>	101
<u>Item 9B. Other Information</u>	102
PART III	102
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	102
<u>Item 11. Executive Compensation</u>	106
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	112
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	114
<u>Item 14. Principal Accounting Fees and Services</u>	115
PART IV	116
<u>Item 15. Exhibits, Financial Statement Schedules</u>	116

Table of Contents

We are subject to federal, state and foreign healthcare and other regulations, including anti-bribery and anti-corruption laws (such as the U.S. Foreign Corrupt Practices Act of 1977), and could face substantial penalties if we fail to comply with such regulations and laws. In particular, the relationships that we, and third parties that market and/or sell our products, have with purchasers of our products, are subject to scrutiny under various state and federal laws, including those referred to collectively as healthcare fraud and abuse laws.

The Company's facilities and operations are subject to various federal, state, and local laws and regulations relating to protection of human health and the environment, including those governing the discharge of pollutants into the environment and the storage, handling, use, treatment, disposal, and recycling of hazardous substances and wastes, as further described below. Such laws include, without limitation, the Clean Air Act, the Clean Water Act, the Toxic Substances Control Act, and the Resource, Conservation, and Recovery Act. As environmental laws and regulations continue to evolve, it is likely the Company will be subject to increasingly stringent environmental standards in the future, particularly under air and water quality laws and standards related to climate change issues. Environmental laws are complex, change frequently and have tended to become increasingly stringent over time.

Analytical Services

Laboratories that provide information included in INDs, NDAs and BLAs must conform to regulatory requirements that are designed to ensure the quality and integrity of the testing process. Most of our contract research services are subject to government standards for laboratory practices that are embodied in regulations for GLP, GMP, BE and GCP. The FDA, Environmental Protection Agency and other regulatory authorities require that test results submitted to such authorities be based on studies conducted in accordance with the regulations listed above. These requirements include but are not restricted to the following areas:

- Resources – organization, personnel, facilities and equipment;
- Rules – protocols and written procedures;
- Characterization – test items and test systems;
- Documentation – raw data, final report and archives; and
- Quality assurance unit – formalized internal audit function.

We must also maintain reports for each study for specified periods for auditing by the study sponsor and by the FDA or similar regulatory authorities in other parts of the world. Regulatory monitoring authorities such as the FDA, have indicated an increased emphasis on the management of electronic records generated by computerized systems to ensure data integrity. Noncompliance with these regulations can result in the disqualification of data collected during the preclinical trial.

Nonclinical Services

Our animal research facilities are subject to a variety of federal and state laws and regulations, including The Animal Welfare Act and the rules and regulations enforced by the United States Department of Agriculture ("USDA") and the National Institutes of Health ("NIH"). These regulations establish the standards for the humane treatment, care and handling of animals by dealers and research facilities. Our animal research facilities maintain detailed standard operating procedures and other documentation necessary to comply with applicable regulations for the humane treatment of the animals in our custody. If the USDA determines that our equipment, facilities, laboratories or processes do not comply with applicable Animal Welfare Act standards, it may issue an inspection report documenting the deficiencies and setting deadlines for any required corrective actions. For continued noncompliance, the USDA may impose fines, suspend and/or revoke animal research licenses or confiscate research animals. In addition to being licensed by the USDA as a research facility, we are also accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International and have registered assurance with the NIH.

Table of Contents

Researchers have increasingly looked for specific ways to interact with the molecular pathways during disease development and progression. This has led to increasing demand for animal models that not only have those same, or similar, pathways, but models that have been altered so that, for example, critical elements of those pathways have been removed or replaced with the human versions. The ability to generate these altered animals relies on molecular tools that can alter the DNA of the animal to achieve the desired model, a so-called ‘transgenic’ animal model. These modified models are becoming increasingly important tools for researchers to better understand disease progression and pathology, and then to develop more highly-targeted therapies.

Envigo's Role in Drug Development

Envigo offers products and services that are critical to drug discovery, development and registration. Discovering and developing new drugs is an expensive and time-consuming process and is highly regulated. Before a new drug reaches commercialization, it must undergo extensive non-clinical and clinical testing to verify that it is safe and effective.

Drug discovery represents the earliest stages of research in new drug development, directed at the identification, screening, and selection of lead molecules for further development. During this stage, new molecules are tested for therapeutic value using various *in silico*, *in vitro* and *in vivo* models. Discovery activities typically extend anywhere from three to six years.

Envigo's laboratory animals and research models are extensively used by academic research centers, government agencies and biopharmaceutical companies engaged in drug discovery. In addition, the Food and Drug Administration (“FDA”) and other regulatory agencies require that the safety and efficacy of new drug candidates be tested in research models like Envigo's prior to product registration. As a result, Envigo's research models are an essential part of the drug research and development process.

Envigo is unique in being the only provider that can supply the whole range of animal model species that regulatory agencies, such as the FDA, require for the safety assessment of both small chemical and biological new drugs.

Research Models and Services (“RMS”)

Envigo's RMS business is comprised of (1) Research Models, (2) Diets and Bedding, and (3) Research Model Services.

Research Models. Envigo's research models business is comprised of the commercial production and sale of laboratory animals and research models, principally purpose-bred rats and mice and large animal models (NHPs, canines and rabbits) for use by researchers. Envigo provides these models to numerous customers around the world, including many academic institutions, government agencies, biopharmaceutical companies, and contract research organizations. Envigo has a global footprint with production facilities strategically located in six countries. Envigo's operations are located in close proximity to our customers, enabling it to provide top-tier customer service with a high degree of animal welfare.

Envigo's research models include standard stocks and strains, immunocompromised models (which are useful for oncology research), disease models (which are in demand as early-stage research tools) and genetically-engineered models (“GEMs”, which are often created for specific research projects).

Small Animal Research Models. Envigo's rodent species have been, and continue to be, some of the most extensively used research models in the world, largely as a result of Envigo's geographic footprint and commitment to quality and customer service. Envigo's products create high customer loyalty, due to the strong preference of customers to avoid variability in their data and to work with an industry founder with more than 90 years of experience. Envigo's small animal research models are bred and maintained in controlled environments, which are designed to ensure that the models are free of specific viral and bacterial agents, and other contaminants that can disrupt research operations and distort research results. With its production capabilities, Envigo strives to consistently deliver high-quality research models worldwide.

Envigo's rodent research models include:

- outbred, which are purposefully bred for heterogeneity;

[Table of Contents](#)

COVID-19 virus continue to emerge and one or more may prove able to partially or fully avoid the protective effect of these vaccines and could prove disruptive in the future.

Due to the world-wide impact of the COVID-19 pandemic, our operations have been impacted in many ways including:

- Disruption in the supply of certain animal research models, including a disruption in the supply of non-human primates (“NHPs”) from China. There is no certainty as to when or if the supply of non-human primates from China will restart;
- Temporary cancellation or delay in customer orders; and
- Product demand fluctuations; and
- Increased supply chain cost and decreased availability

Envigo has been able to secure NHPs from other sources in Asia to cover a large portion of NHPs typically sourced from China, but customer demand continues to outpace supply.

Executive Officers of the Registrant

The following table provides information concerning the persons who currently serve as our executive officers. Officers are elected annually at the annual meeting of the board of directors.

Name	Age	Position
Robert W. Leasure, Jr.	62	President and Chief Executive Officer
John E. Sagartz, DVM, Ph.D., DACVP	57	Chief Strategy Officer
Beth A. Taylor	56	Chief Financial Officer, Vice President-Finance
William D. Pitchford	67	Chief Human Resources Officer
John Gregory Beattie	54	Chief Operating Officer
Philip A. Downing	52	Senior Vice President, Preclinical Services
Adrian Hardy, Ph.D.	51	Executive Vice President
James Harkness	56	Chief Operating Officer, Research Models & Services
Michael Garrett	54	Chief Commercial Officer
Mark Bibi	63	General Counsel & Secretary

Robert W. Leasure, Jr. joined the Company as President and Chief Executive Officer on January 12, 2019. Mr. Leasure serves as the managing partner and president of LS Associates LLC (“LS”), a management and turnaround firm formed in 2002. From September 2016 until Mr. Leasure’s employment, the Company engaged LS as a financial consultant. Mr. Leasure’s experience working with management teams in areas including strategic planning and implementation, problem solving, operations, mergers and acquisitions and financial transactions, and in particular Mr. Leasure’s experience leading the Company’s turnaround and current growth, well situate him for his role as President and Chief Executive Officer and as a director.

John E. Sagartz, DVM, Ph.D., DACVP, joined the Company as part of the Company’s acquisition of Seventh Wave Laboratories on July 2, 2018. Following the acquisition, Dr. Sagartz has served as the Company’s Chief Strategy Officer and joined Inotiv’s Board of Directors to help guide strategy in order to provide broader solutions and greater scientific expertise to the Company’s clients. Dr. Sagartz began his career as a toxicologic pathologist at Searle/Monsanto

[Table of Contents](#)**Any failure by us to comply with existing regulations could harm our reputation and operating results.**

Any failure on our part to comply with existing regulations could result in the termination of ongoing research or the disqualification of data for submission to regulatory authorities. For example, if we were to fail to properly monitor compliance with study protocols, the data collected could be disqualified. Under such circumstances, we may be contractually required to repeat a study at no further cost to the client, but at substantial cost to us. That development would harm our reputation, our prospects for future work and our operating results. Furthermore, the issuance of a notice from the FDA or the USDA based on a finding of a material violation by us of good clinical practice, good laboratory practice or good manufacturing practice requirements or other applicable regulations could materially and adversely affect our business and financial performance.

Privacy regulations could increase our costs or limit our services.

U.S. Department of Health and Human Services regulations under the Health Insurance Portability and Accountability Act of 1996 demand compliance with patient privacy and confidentiality requirements. In addition, some state governments are considering more stringent regulations. The General Data Protection Regulation (GDPR), which became effective in May 2018, imposes heightened obligations on businesses that control and manage the personal data of E.U. citizens. These and similar regulations might require us to increase our investment in security or limit the services we offer. We could be found liable if we fail to meet existing or proposed regulations on privacy and security of health information.

Risks Related to Research and Development**Our future success depends on our ability to keep pace with rapid technological changes that could make our services and products less competitive or obsolete.**

The biotechnology, pharmaceutical and medical device industries generally, and contract research services more specifically, are subject to increasingly rapid technological changes. Our competitors or others might develop technologies, services or products that are more effective or commercially attractive than our current or future technologies, services or products, or that render our technologies, services or products less competitive or obsolete. If competitors introduce superior technologies, services or products and we cannot make enhancements to our counterparts to remain competitive, our competitive position, and in turn our business, revenues and financial condition, would be materially and adversely affected. Many of our competitors have superior financial and human resources deployed toward research and development efforts. Our relatively constrained financial and human resources may limit our ability to effectively keep pace with relevant technological changes.

We may incur expenses on potential products that we never successfully develop or commercialize.

We have incurred and expect to continue to incur research and development and other expenses in connection with our Products business. We might never successfully develop or commercialize potential products to which we devote resources for numerous reasons, including:

- inability to develop products that address our clients' needs;
- competitive products with superior performance;
- patent conflicts or unenforceable intellectual property rights;
- demand for the particular product; and
- other factors that could make the product uneconomical.

Incurring expenses for a potential product that is not successfully developed and/or commercialized could have a material adverse effect on our business, financial condition, prospects and stock price.

[Table of Contents](#)

- performance shortfalls as a result of the diversion of management's attention caused by completing the Envigo Acquisition and integrating Envigo's operations; and
- the disruption of, or the loss of momentum in, Inotiv's ongoing business or inconsistencies in standards, controls, procedures and policies.

We may not be able to accomplish this integration process successfully.

Our results may suffer if we do not effectively manage our expanded operations following the Envigo Acquisition.

As a result of the Envigo Acquisition, the size and scope of our business increased significantly beyond its previous size. Our future success will depend, in part, on our ability to manage this expanded business, which poses numerous risks and uncertainties, including the need to integrate the operations and business of Envigo into our existing business in an efficient and timely manner, to combine systems and management controls and to integrate relationships with customers, vendors and business partners.

Actions of animal rights activists may affect our business.

Envigo's RMS business provides animal research models to our customers. Such activities are required for the registration of products under regulatory regimes in the United States, Europe and other countries. Many CROs, biopharmaceutical companies and other research organizations have been targeted by animal rights activists who oppose all testing on animals, for whatever purpose, including the animal testing activities in support of safety and efficacy testing for drug development. These groups, which include groups directed at the industry and us, have publicly stated that the goal of their campaign is to stop animal testing. Acts of vandalism and other acts by animal rights activists who object to the use of animals in product development could have a material adverse effect on our business. These groups have historically targeted CROs, academic institutions and biopharmaceutical companies, but also third parties that do business with CROs, academic institutions and biopharmaceutical companies, including customers, suppliers, advisors, financial advisors, lenders and investors.

We are subject to periodic inspections by regulatory authorities which could lead to enforcement actions if those authorities determine that our facilities or procedures do not meet applicable requirements.

We are subject to periodic inspections by regulatory authorities, including the FDA and the USDA. As part of these inspections, the regulatory authorities seek to determine whether our facilities and operations comply with applicable laws and regulations. Adverse findings as a result of these inspections could lead to enforcement actions, including substantial fines, warning letters that require corrective action (including potential facilities improvement requirements), revocation of approvals, exclusion from future participation in government healthcare programs, criminal prosecution and even the denial of the right to conduct business. During the period from July through December 2021, one of the Envigo's U.S. facilities was inspected on several occasions by the USDA. Following the inspection, USDA issued inspection reports with findings of non-compliance with certain USDA laws and regulations. Envigo formally appealed certain of the findings and the USDA has indicated it intends to conduct a formal investigation. The inspections and/or the investigation could lead to enforcement action resulting in penalties that could include a temporary restraining order or injunction, civil and/or criminal penalties, and/or license suspension or revocation. The imposition of any of these penalties or other restrictions on our business as a result of the inspections could adversely affect our business reputation and could have a material adverse impact on our financial condition, results of operations and stock price.

Our principal shareholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to shareholder approval.

As of December 1, 2021, our executive officers, directors and 5% shareholders beneficially owned approximately 37.0% of the outstanding shares of capital stock. In addition, as of December 1, 2021, our executive officers and directors held options to purchase an aggregate of 747,075 of our common shares at a weighted-average exercise price of \$7.83 per share. Therefore, these shareholders will have the ability to influence us through this ownership position. The interests of this group of shareholders may not coincide with the interests of other shareholders.

[Table of Contents](#)

in cash from operations as compared to \$1,290 in the same period in fiscal 2020. Total capital expenditures were \$12,472 in fiscal 2021 primarily due to investments in the acquisition and expansion of the St. Louis facility, facility improvements at the Fort Collins location and investments in laboratory equipment to increase capacity at all locations.

As of September 30, 2021, we did not have an outstanding balance on our \$5,000 general line of credit, and we had a \$1,749 balance on our \$3,000 capex line of credit. As described herein, we incurred indebtedness in connection with financing acquisitions and planned expansions of facilities and services. Please refer to the Liquidity and Capital Resources section herein for a description of our credit agreements.

In fiscal 2022, we expect certain trends and risks to potentially affect our business. General risks to the company are shared by the industry as well. Increased demand and decreased supply of certain critical research models affects the ability to procure these models in support of our clients' projects. The acquisition of Envigo enhances our ability to secure access to these critical resources. We expect also to see inflationary impacts on costs of supplies and wage inflation, particularly affecting entry to mid-level positions, with a subsequent impact on pricing. We expect continued challenges in hiring staff at all levels.

For a detailed discussion of our revenue, margins, earnings and other financial results for fiscal 2021, see "Results of Operations" below.

Results of Operations

The following table summarizes the consolidated statement of operations as a percentage of total revenues:

	Year Ended September 30,	
	2021	2020
Services revenue	95.8 %	94.6 %
Products revenue	4.2	5.4
Total revenue	100.0 %	100.0 %
Cost of services revenue (a)	66.7	70.0
Cost of products revenue (a)	58.0	67.6
Total cost of revenue	66.3	69.8
Gross profit	33.7	30.2
Operating expenses	39.9	35.2
Operating loss	(6.3)	(5.1)
Other income (expense)	13.1	(2.4)
Income (loss) before income taxes	6.8	(7.5)
Income tax benefit	(5.3)	0.2
Net income (loss)	12.2 %	(7.7)%

(a) Percentage of service and product revenues, respectively.

Fiscal 2021 Compared to Fiscal 2020

Services and Products Revenues

Revenues for the fiscal year ended September 30, 2021 increased 48.2% to \$89,605 compared to \$60,469 for the fiscal year ended September 30, 2020.

Our Services revenue increased 50.1% in fiscal 2021 to \$85,832 compared to \$57,177 for the prior fiscal year. Nonclinical services revenues increased due to internal growth year over year as well as the acquisition of substantially all